IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CARDINAL HEALTH, INC., Petitioner, v. NATIONAL BOARD OF MEDICAL EXAMINERS, Respondent.	Civil Action No. _____

MEMORANDUM IN SUPPORT OF MOTION TO COMPEL DISCOVERY RESPONSES FROM NATIONAL BOARD OF MEDICAL EXAMINERS

Petitioner Cardinal Health, Inc., one of the nation's leading distributors of medical and pharmaceutical products, is named in thousands of cases around the country alleging that it and its fellow distributors caused the nation's opioid epidemic.[1] Central to those cases is this question: Why did America's doctors write the number of opioid prescriptions that they did? To answer it, one must understand what aspiring doctors were taught and expected to know about opioids.

Every would-be medical doctor in the country must take a licensing exam overseen by the National Board of Medical Examiners (NBME). NMBE's past exams will show what prospective doctors had to know about opioids and pain management before they could be licensed—and, in turn, why those doctors later prescribed opioids at the rate they did. Petitioner therefore subpoenaed documents from NBME about the content and review of the exams. But

[1] In addition to Cardinal Health, Inc., the defendants in the action in which the subject subpoena was issued are AmerisourceBergen Drug Corporation (of Chesterbrook, Pennsylvania), and McKesson Corporation.

NBME seeks to keep the exams secret, even in the midst of immensely consequential litigation regarding a major societal problem. It refuses to produce them despite the existence of a strong protective order designed for just these circumstances. NBME's insistence on secrecy for this evidence, which is not subject to any privilege, lacks any legal support. For that reason (and to ensure the production of a closely related category of documents that NBME agrees it must produce but has not yet turned over), Petitioner seeks to compel compliance with their document subpoena to NBME.[2]

The subpoena to NBME was issued in the Southern District of West Virginia, where two cases remanded from the national prescription opiate multidistrict litigation are pending trial.[3] Petitioner has filed this motion in this Court because NBME is based in Philadelphia. But because of the exceptional circumstances of the MDL and the underlying cases, this motion should be transferred to the Southern District of West Virginia.

I. The Court Should Transfer this Motion to the Issuing Court.

Under Rule 45(d)(2)(i), a party that has served a subpoena "may move the court for the district where compliance is required for an order compelling production." However, under Rule 45(f), this Court may transfer this motion to the issuing court "if the court finds exceptional circumstances." For example, "transfer may be warranted in order to avoid disrupting the issuing court's management of the underlying litigation." Fed. R. Civ. P. 45, committee notes on 2013 amend.

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[2] A copy of the subpoena is attached as Exhibit A.

[3] The cases are *The City of Huntington v. AmerisourceBergen Drug Corp.*, No. 3:17-cv-1362 (S.D. W. Va.), and *Cabell County Commission v. AmerisourceBergen Drug Corp.* No. 3:17-cv-1665 (S.D. W. Va.). The MDL is *In Re National Prescription Opiate Litigation*, MDL No. 2804 (N.D Ohio).

Petitioner contends that this motion should be transferred to the issuing court. "Transfer is necessary to allow the court that is most familiar with [the] core arguments … to evaluate the importance of the documents sought in the subpoenas at issue to those core arguments." *In re Braden*, 344 F. Supp. 3d 83, 94 (D.D.C. 2018). Accordingly, "[t]he centrality of the relevance assessment weighs in favor of transfer because determining whether information is relevant requires 'nuanced legal analysis based on a full understanding of the Underlying Action.'" *Lipman v. Antoon*, 284 F. Supp. 3d 8, 13 (D.D.C. 2018) (internal citations omitted). District Courts in the Third Circuit tend to transfer subpoena-related motions to the issuing court when they "are best addressed . . . within the context of the underlying dispute." *Bouchard Transp. Co. v. Associated Elec. & Gas Ins. Servs. Ltd.*, No. 15CV3709SRCCLW, 2015 WL 12818828, at *3 (D.N.J. Aug. 4, 2015); *see also Genesis Abstract, LLC v. Bibby*, No. CV 17-302 (RBK/AMD), 2017 WL 1382023, at *2 (D.N.J. Apr. 18, 2017) (transferring subpoena-related motion where issuing court had established a discovery schedule and a dispute resolution procedure which involved continuing management by a Special Master because "the Court [was] loath to disturb those structures, especially considering the long history and complexity of the litigation"). It is this Court's practice to transfer subpoena-related motions when the nature of the underlying litigation is complex and there has been focused management of discovery—as evidence by a scheduling order with tight deadlines—and engagement by another court "is likely to disrupt that calibration." *See, e.g., Meijer Inc., et al. v. Ranbaxy Inc., et al.*, No. MC 17-91, 2017 WL 2591937, at *3 (E.D. Pa. June 15, 2017). Furthermore, any burden on the subpoenaed party from transferring is lessened by the fact that "[i]n light of current events, [a] Court would certainly expect that telecommunications methods would be the most appropriate way to address this discovery issue if an appearance is necessary." *In re Nonparty Subpoenas to PPG Indus.,*

Inc., No. 2:20-MC-00296-RJC, 2020 WL 1445844, at *4 (W.D. Pa. Mar. 25, 2020) (citing Fed. R. Civ. P. 45 Advisory Committee's Note to 2013 Amend.).

Multiple independent reasons support transfer here. The history and complexity of the opioid litigation, the involvement of a Special Master who has background knowledge and established discovery procedures to evaluate discovery issues under a tight schedule, and the centrality of the relevancy dispute to this motion each warrant transfer to Judge David A. Faber and Special Master Christopher C. Wilkes in the Southern District of West Virginia.

II. In the Alternative, the Court Should Enforce the Subpoena.

Should this Court decide to retain jurisdiction over this motion, the Court should enforce the subpoena.

A. Background

The NBME develops a number of assessments used in medical education, licensure, and certification, including chiefly the United States Medical Licensing Examination ("USMLE"), a three-step examination required by all state medical boards to license physicians across the United States.[4] There is one national exam to ensure that all licensed physicians pass the same assessment standards.[5] The USMLE was first designed in the late 1980s and introduced from 1992 to 1994. The content and questions on the exam evolve yearly as technological advances occur and the standards of care in the medical profession change. The test covers various competencies, and includes questions related to pain and pain management.

The standard of care for the treatment of pain—and, in particular, chronic non-cancer pain—has changed dramatically over the past 30 years. Until the mid- to late-1990s, opioid

[4] *Who is USMLE?* https://www.usmle.org/about/ (last visited May 13, 2020).

[5] *Id.*

medications were prescribed only to treat acute or cancer-related pain, or at the end of life. By the mid- to late-1990s, however, the medical community recognized that chronic *non-cancer* pain was being under-treated, and came to believe that opioid medications were a safe and effective means of pain management for that large, previously untreated group of patients. This new focus on the under-treatment of chronic pain caused a significant increase in legitimate opioid prescribing, because opioids were, as a practical matter, the most readily available and accessible means to treat pain. The increased volume of prescriptions resulted in a significant increase in orders of opioid medications from state-licensed, DEA-registered pharmacies and hospitals and a significant increase in shipments by wholesale distributors. The change in the standard of care explains why the rise in distributions of opioid medications was not suspicious, as Plaintiffs allege, but rather a direct result of contemporaneous developments within the medical community. Conversely, in recent years, the standard of care has become more restrictive with respect to the prescribing of opioid medications to treat chronic pain. As opioid prescribing has decreased, so too have orders from pharmacies and, in turn, shipments by distributors.

Given the centrality of this changing standard of care to understanding the volume of opioid distributions, Petitioner subpoenaed information from the NBME regarding the testing and grading of content related to pain management. Petitioner served the subpoena on NBME on March 27, 2020, and the subpoena called for production of documents by April 14. In early April, a representative of NBME contacted Petitioner's counsel to seek clarification and request additional time to respond to the subpoena due to the COVID-19 public health crisis. Exhibit B. Petitioner agreed to be flexible on the deadline. On April 10, however, NBME's outside counsel, Perkins Coie LLP, sent Petitioner a letter with blanket objections to all of the document

requests. Exhibit C. Petitioner met and conferred with NBME's outside counsel on April 14. While maintaining its other objections, NBME agreed to produce a discrete set of documents to Petitioner relating to two public, external reviews of USMLE test questions related to pain—one by the Interprofessional Pain Management Competency Program in November 2014, and the other by the American Academy of Hospice and Palliative Medicine in June 2016. NBME subsequently produced 14 documents relating to these reviews, but NBME did not produce any other documents responsive to the subpoena.

Petitioner and NBME met and conferred again after NBME produced the 14 documents, and, in an effort to streamline compliance as much as possible, Petitioner narrowed its requests to only two further categories of materials:

(1) Documents and correspondence relating to (a) the Interprofessional Pain Management Competency Program's November 2014 review of USMLE test questions related to pain, and (b) the American Academy of Hospice and Palliative Medicine's June 2016 review of USMLE test questions related to pain;[6] and

(2) All USMLE test questions relating to pain management (and documents reflecting the correct answers).[7]

[6] Petitioner met and conferred with NBME on May 14, and NBME committed orally to undertake a reasonable effort to search for and produce documents and communications responsive to this request. Because May 15 is the deadline for discovery motions pursuant to a recent order by the issuing Court, Petitioner nonetheless submits this issue.

[7] These two categories fall squarely within the Request No. 7 of the subpoena: "All Documents and Communications relating to the testing and grading of content related to pain management (including the monitoring, measuring, and treatment of pain by healthcare professionals) and/or Prescription Opioids on the United States Medical Licensing Examination (USMLE) and other medical licensing examinations."

B. Argument

The materials Petitioner requests from NBME are relevant and discoverable. "As provided in Rule 45, a nonparty may be compelled to produce documents." Fed. R. Civ. P. 34(c). "When a subpoena is issued under Rule 45 for the purpose of discovery, Rule 45 adopts the standard[s] codified in Rule 26." *JAK Prods., Inc. v. Robert Bayer*, No. 2:15-CV-00361, 2015 WL 2452986, at *9 (S.D. W. Va. May 22, 2015) (internal quotations marks and citations omitted). Rule 26(b)(1) provides: "Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). "[R]elevancy encompasses any matter that bears or may bear on any issue that is or may be in the case … Although the pleadings are the starting point from which relevancy and discovery are determined … relevancy is not limited by the exact issues identified in the pleadings, the merits of the case, or the admissibility of discovered information. Rather, the general subject matter of the litigation governs the scope of relevant information for discovery purposes." *JAK Prods., Inc.*, at *9 (internal citations omitted).

C. The Court Should Compel Production of NBME's Documents and Correspondence Relating to the Reviews of USMLE Test Questions on Pain.

NBME produced 14 documents relating to the Interprofessional Pain Management Competency Program's November 2014 review and the American Academy of Hospice and Palliative Medicine's June 2016 review. This small production has left Petitioner with more questions than answers about this highly relevant line of discovery. The documents demonstrate

that the USMLE's testing of pain has been the subject of extensive scrutiny and debate in the medical community. For example, a publicly available report by the experts who conducted the November 2014 review found that, "despite ample numbers of questions related to pain in the USMLE, pain assessment was disproportionately represented compared with the nature and context of pain, or how pain can be safely and effectively treated."[8] Petitioner is entitled to discover communications regarding how those external reviews came about, what the NBME thought about these exercises at the time, and what the NBME did afterward with the results. Such contextual documents and correspondence will shed light on NBME's handling of the reviews of USMLE content related to pain, which is directly relevant to the evolving standard of care regarding pain management. Therefore, as Petitioner explained to NBME earlier this week, Petitioner is seeking any further documents or correspondence (including internal or external emails) relating to the Interprofessional Pain Management Competency Program's November 2014 review and the American Academy of Hospice and Palliative Medicine's June 2016 review.

NBME's general objections regarding burden and expense do not justify its refusal to produce discovery in response to this narrow request. The documents produced to date confirm the highly relevant nature of these issues, and there is no substitute for obtaining communications and other NBME documents regarding these reviews. NBME does not dispute its obligation to produce the documents in this category, and this motion addresses them only to ensure that the production is completed.

[8] Scott M. Fishman, MD, et al., *Scope and Nature of Pain- and Analgesia-Related Content of the United States Medical Licensing Examination (USMLE),* Pain Medicine (United States), 19(3), 449-459 (2018) (attached as Exhibit D).

D. The Court Should Compel Production of USMLE Test Questions on Pain Management.

Petitioner requested information from NMBE about USMLE test questions on pain management because, as the sole national examination for licensed physicians, the USLME questions presumably reflect the then-existing standards of care within the medical community across all topics, including pain management. Critical to this case is an understanding of what caused the rising prescriptions in Plaintiffs' jurisdictions and whether, as Plaintiffs allege, such an increase in prescriptions (and corresponding increase in orders from Petitioner, which distributed the prescribed medication) should have raised concerns. The ways in which the NBME has (and has not) chosen to test pain management and adjust that testing over the years is central to understanding how the standard of care regarding pain management evolved during the relevant time period, and is highly relevant to Defendants' causation defenses. Petitioner thus is entitled to assess USMLE test questions related to pain management.

NBME suggests that USMLE test content is protected from disclosure in this litigation, but its assertion is unfounded. Rule 45(d)(3)(B)(i) states that the court *may,* on motion, quash or modify the subpoena if it requires: "(i) disclosing a trade secret or other confidential research, development, or commercial information." However, "[i]nformation and documents are not shielded from discovery merely because they are confidential," and the better course is to designate documents as "confidential" subject to a protective order. *See In re C.R. Bard, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 287 F.R.D. 377, 384 (S.D. W. Va. 2012) (citation omitted) (enforcing subpoena against third party where serving party offered opportunity to designate some documents as "confidential" pursuant to protective order entered in MDL and third party had not yet met its burden of showing that its documents were in fact trade secrets or other confidential research, development, or commercial information). Many parties and non-

parties have produced highly sensitive information pursuant to the Protective Order applicable in this case. Petitioner understands the importance of maintaining the confidentiality of USMLE content for protecting the integrity of exam results. But that does not excuse NBME from producing USMLE content here. As the subpoena instructs, NBME can designate produced materials as "confidential" pursuant to the Protective Order, just as NBME has done with the other documents it has produced. As NBME is aware, the Protective Order provides multiple layers of protection, including limiting disclosure of designated documents. Exhibit E ¶¶ 32-34.

The Court should reject any argument that burden or expense justifies NBME's refusal to produce these documents. Petitioner has narrowed its original subpoena to focus on the most critical issues. Petitioner has also attempted to reduce any burden on NBME arising from this request: In the process of meeting and conferring, Petitioner inquired as to NBME's position on producing three sub-categories of USMLE questions: (1) questions that have been retired from use on the USMLE due to age, obsolescence, or some other reason; (2) questions that were tested on the USMLE but not scored for psychometric or other reasons; and (3) questions that were previously disseminated to the public as samples. NBME has not committed to producing any of those types of questions, even though it acknowledges that they are subject to a lesser degree of confidentiality than its "live" test questions. Petitioner needs to see USMLE test questions and answers relating to pain management to determine how this subject has been tested over time. Assuming NBME maintains an electronic database of USMLE test questions, it should not be difficult to search for and produce those related to pain management. If it would be less burdensome for NBME to produce full examinations, Petitioner would accept those instead.

III. Conclusion

For the reasons set forth above, the Court should transfer this motion to the issuing court in the Southern District of West Virginia, or in the alternative, grant Petitioner's Motion to

Compel and order NBME to promptly produce all documents responsive to Petitioner's two narrowed requests.

Dated: May 15, 2020

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Patricia Mulvoy Kipnis, counsel for Cardinal Health, Inc. do hereby certify that on This 15th day of May, 2015, the foregoing **MEMORANDUM IN SUPPORT OF MOTION TO COMPEL DISCOVERY RESPONSES FROM NATIONAL BOARD OF MEDICAL EXAMINERS** was filed electronically via the CM/ECF electronic filing system and served via First Class United State Mail, postage pre-paid on counsel for the Respondent.

/s/ Patricia Mulvoy Kipnis